

Practitioner's Docket No. 142/003/PCT

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Light, Elizabeth S.; Nuovo, Gerard J.

Int. Application No.: PCT/US99/25109

USSN: 09/582,492

Filed: 26-OCT-1999

For: Detection of Human Papilloma Virus in Papanicolau (Pap) Smears

RECEIVED

JUN 19 2001

Technology Center 2600

RESPONSE TO NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN  
THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

Box PCT  
Assistant Commissioner for Patents  
Washington, D.C. 20231

In response to the Notification of Missing Requirements Under 35 U.S.C. 371 in the United States Designated/Elected Office (DO/EO/US) dated April 20, 2001 ("Notification"), Applicants believe that it was sent in error due to a previous error of Applicants. A phone call to the PCT Branch resulted in Applicants being instructed to file corrected papers to resolve the issues raised (see the attached Explanation and Acknowledgement of Incorrect International Application Numbers on Certain Papers). In short, the Notification asserted that the Declaration did not comply with 37 CFR 1.497 (a) and (b). Applicants, having inspected the Declaration submitted June 26, 2000 and finding it to be in compliance, then discovered that the mis-identified papers (Transmittals, Small Entity Statement, Petition for Extension of Time to Reply, and Response to Invitation to Correct Defects) likely led to the Notification being incorrect.

Therefor, in response to the Notification, enclosed are copies of the following documents:

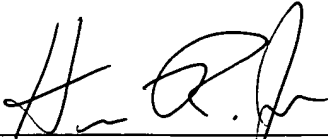
- (1) Copy of Notification of Missing Requirements Under 35 U.S.C. 371 in the United States Designated/Elected Office (DO/EO/US);
- (2) Explanation and Acknowledgement of Incorrect International Application Number, addressed to: PCT LEGAL, Assistant Commissioner of Patents, Washington, D.C. 20231;
- (3) Corrected Transmittal Letter to the U.S. Designated Office (DO/US) - Entry into the U.S. National Phase Under Chapter I dated June 26, 2000;

- (4) Corrected Statement Claiming Small Entity Status;
- (5) Corrected Transmittal Letter dated September 11, 2000;
- (6) Corrected Response to Invitation to Correct Defects in International Application;
- (7) Corrected Petition and Fee for Extension of Time; and
- (8) Postcard

The documents in the above list that are indicated as "Corrected" should be forwarded to PCT Legal in the envelope in which they are being sent.

Date: 5-21-01

Reg. No.: 33,916  
Tel. No.: 520-408-6350  
Customer No.: 23874

  
\_\_\_\_\_  
Signature of Practitioner

Huw R. Jones  
Ventana Medical Systems, Inc.  
3865 N. Business Center Drive  
Tucson, AZ 85705

**Practitioner's Docket No. 142/003/PCT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: Light, Elizabeth S.; Nuovo, Gerard J.

Application No.: PCT/US99/25109

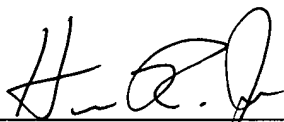
Filed: 26-OCT-1999

For: **Detection of Human Papilloma Virus in Papanicolau (Pap) Smears**

**RESPONSE TO INVNTATION TO CORRECT DEFECTS  
IN INTERNATIONAL APPLICATION**

**Assistant Commissioner for Patents  
Washington, D.C. 20231**

With respect to the Invitation to Correct Defects in the International Application, attached is a copy of the Combined Declaration and Power of Attorney, which was filed in this case. Please be advised that all Applicants in this matter have signed the Combined Declaration and Power of Attorney.

  
\_\_\_\_\_  
SIGNATURE OF PRACTITIONER

Reg. No. 33,916

Tel. No.: (520) 408-6350

Customer No.: 23874

Date: September 11, 2000

Huw R. Jones, Esq.  
Ventana Medical Systems, Inc.  
3865 N. Business Center Drive  
Tucson, AZ 85705



UNITED STATES PATENT AND TRADEMARK OFFICE

R	APR 26 1999	U
VENTANA MEDICAL SYSTEMS, INC. LEGAL DEPARTMENT		

Commissioner for Patents, Box PCT  
United States Patent and Trademark Office  
Washington, D.C. 20231  
www.uspto.gov

U.S. APPLICATION NO.	FIRST NAME OF APPLICANT	ATTY. DOCKET NO.
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09/582492

LIGHT

E

142/003/PCT

INTERNATIONAL APPLICATION NO.

PCT/US99/23805

I.A. FILING DATE

PRIORITY DATE

26 OCT 99

26 JAN 98

DATE MAILED:

20 APR 2001

**NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)**

1. The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as ☐ a Designated Office (37 CFR 1.494) ☒ an Elected Office (37 CFR 1.495):

- |   |   |
|---|---|
| <input checked="" type="checkbox"/> U.S. Basic National Fee.  | <input checked="" type="checkbox"/> Indication of Small Entity Status.              |
| <input checked="" type="checkbox"/> Copy of the international application.  | <input type="checkbox"/> Translation of the international application into English. |
| <input checked="" type="checkbox"/> Oath or Declaration of inventors(s).  | <input type="checkbox"/> Translation of Article 19 amendments into English.         |
| <input type="checkbox"/> Copy of Article 19 amendments.   | <input type="checkbox"/> Other:   |
| <input type="checkbox"/> Priority Document.   |   |
| <input type="checkbox"/> The International Preliminary Examination Report in English and its Annexes, if any.     |   |
| <input type="checkbox"/> Translation of Annexes to the International Preliminary Examination Report into English. |   |

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Technology Center 2600

2. ☐ Applicant has requested early processing under 35 U.S.C. 371(f) but has not filed the following indicated items and/or the indicated items in paragraph 3 below. The Basic National Fee and the copy of the international application must be filed prior to 20 or 30 months from the priority date to avoid abandonment.

- ☐ U.S. Basic National Fee. ☐ Copy of the international application.

3. The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- ☐ a. Translation of the application into English. A processing fee will be required if submitted later than the appropriate 20 or 30 months from the priority date.
- ☐ The current translation is defective for the reasons indicated on the attached Notice of Defective Translation.
- ☐ b. Processing fee for providing the translation of the application and/or the Annexes later than the appropriate 20 or 30 months from the priority date (37 CFR 1.492(f)).
- ☒ c. Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), properly identifying the application (preferably by the International application number and international filing date). A surcharge will be required if submitted later than the appropriate 20 or 30 months from the priority date.
- ☒ The current oath or declaration does not comply with 37 CFR 1.497(a) and (b) for the reasons indicated on the attached PCT/DO/EO/917.
- ☐ d. Surcharge for providing the oath or declaration later than the appropriate 20 or 30 months from the priority date (37 CFR 1.492(e)).

4. Additional claim fees of \$\_\_\_\_\_ as a ☐ large entity ☐ small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due (37 CFR 1.492(g)). See attached PTO-875.

5. ☐ Applicant has not submitted the required sequence listing pursuant to 37 CFR 1.821-1.825. See attached PCT/DO/EO/920.

**ALL OF THE ITEMS SET FORTH IN 3(a)-3(d), 4 AND 5 ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 22 OR 32 MONTHS (where 37 CFR 1.495 applies) FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

6. If box 3a or 3c is checked, a translation of the Annexes **MUST** be submitted no later than the time period set above or the Annexes will be cancelled. A processing fee will be required if submitted later than 20 or 30 months from the priority date.

7. ☐ The Article 19 amendments are cancelled since a translation was not provided by the appropriate 20 (37 CFR 1.494(d)) or 30 (37 CFR 1.495(d)) months from the priority date.

Applicant is reminded that any communication to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above. (37 CFR 1.5)

**A copy of this notice MUST be returned with this response.**

Enclosed: ☒ PCT/DO/EO/917 ☐ Notice of Defective Translation  
☐ PTO-875 ☐ PCT/DO/EO/920

India Evans

FORM PCT/DO/EO/905 (March 2001)

Telephone: 703-305-2936



## UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents, Box PCT  
United States Patent and Trademark Office  
Washington, D.C. 20231  
www.uspto.gov

U.S. APPLICATION NO.	FIRST NAMED APPLICANT	ATTY. TICKET NO.
09/582492	LIGHT	E 142/003/PCT
INTERNATIONAL APPLICATION NO.		
PCT/US99/23805		
I.A. FILING DATE	PRIORITY DATE	
26 OCT 99	26 JAN 98	

HUW R JONES, ESQ  
VENTANA MEDICAL SYSTEMS, INC.  
3865 NORTH BUSINESS CENTER DRIVE  
TUCSON, AZ 85705

DATE MAILED: 20 APR 2001

## NOTIFICATION OF A DEFECTIVE OATH OR DECLARATION

This application fails to contain an oath or declaration acceptable under 35 U.S.C. 371(c)(4) for entry into the national stage in the United States of America. The period within which to correct the deficiency noted below and avoid abandonment is set in the accompanying Notification.

A new oath or declaration, properly identifying this application (preferably by the international application number and international filing date) is required. The oath or declaration does not comply with 37 CFR 1.497(a),(b) and (f) in that it:

1. ☐ is not executed in accordance with either 37 CFR 1.66 or 37 CFR 1.68.
2. ☒ does not identify the application to which it is directed.
3. ☐ does not identify the inventor(s).
4. ☐ does not identify the citizenship of each inventor.
5. ☐ does not state that the person making the oath or declaration believes the named inventor or inventors to be the original and first inventor or inventors of the subject matter which is claimed and for which a patent is sought.

\*none of the info sent in for the above serial number match the PCT number listed on the applicant's transmittal letter.

FAILURE TO SUBMIT AN OATH OR DECLARATION IN COMPLIANCE WITH 37 CFR 1.497(a) AND (b), AND 1.497(d) WHERE APPROPRIATE, WITHIN THE TIME PERIOD SET WILL RESULT IN FAILURE TO ENTER THE NATIONAL STAGE AND THE ABANDONMENT OF THE APPLICATION.

Additionally, the oath or declaration does not comply with 37 CFR 1.63 in that it:

1. ☐ does not identify the mailing address of each inventor. If the residence is different from the mailing address, then the city and state or city and foreign country of residence of each inventor must also be given.
2. ☐ does not state that the person making the oath or declaration:
  - a. ☐ has reviewed and understands the contents of the application, including the claims, as amended by any amendment specifically referred to in the oath or declaration.
  - b. ☐ acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.
3. ☐ does not identify the foreign application for patent or inventor's certificate for which a claim for priority is made pursuant to 37 CFR 1.55, and any foreign application having a filing date before that of the application on which priority is claimed, by specifying the application serial number, country, day, month, and year of its filing.

India Evans

Telephone: 703-305-2936

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Light, Elizabeth S.; Nuovó, Gerard J.

Application No.: PCT/US99/25109

Filed: 26-OCT-1999

For: Detection of Human Papilloma Virus in Papanicolaou (Pap) Smears

EXPLANATION AND ACKNOWLEDGEMENT OF  
INCORRECT INTERNATIONAL APPLICATION NUMBER ON CERTAIN PAPERS

PCT LEGAL  
Assistant Commissioner for Patents  
Washington, D.C. 20231

With respect to certain papers filed during entry of the above-captioned international application through Ch. I in the DO/EO/US, please be advised of the following:

1. On June 26, 2000, the following documents were submitted to the Commissioner of Patents and Trademarks:
  - (a) Docket No. 142/003/PCT - Transmittal Letter to the U.S. Designated Office (DO/US) - Entry into the U.S. National Phase Under Chapter I (duplicate);
  - (b) Combined Declaration and Power of Attorney;
  - (c) Small Entity Statement containing Application No. PCT/US99/23815; and
  - (d) Post Card
2. On September 14, 2000, the following documents were submitted to the Commissioner of Patents and Trademarks:
  - (a) Transmittal Letter to the U.S. Designated Office containing Application No. PCT/US99/23815;
  - (b) Response to Invitation to Correct Defects in International Application containing Application No. PCT/US99/23815;
  - (c) Petition and Fee for Extension of Time containing Application No. PCT/US99/23815; and

(d) Post Card

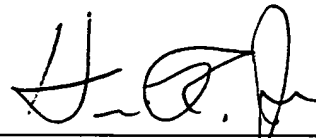
3. Some of the aforementioned papers incorrectly identified the International Application as PCT/US99/23815, when in fact the number should have been indicated as PCT/US99/25109. Others showed the Practitioner's Docket No. 142/003/PCT as the International Application Number.
4. The correct International Application Number is PCT/US99/25109, which corresponds to USSN 09/582,492, Attorney Docket No. 142/003/PCT.
5. Enclosed with this explanation are the following corrected documents:
  - (a) June 26, 2000 re-submitted corrected documents
    - (i) Transmittal letter - Entry into U.S. National Phase
    - (ii) Small Entity Statement
  - (b) September 11, 2000 re-submitted corrected documents
    - (i) Transmittal letter to the US/DO
    - (ii) Response to Invitation to Correct Defects
    - (iii) Petition and Fee for Extension of Time
6. The Combined Declaration and Power of Attorney originally filed June 26, 2000 correctly identified the International Application Number and Attorney Docket Number. As such, the Notification of a Defective Oath or Declaration dated April 20, 2001 was sent in error.

We respectfully request that these documents be submitted to the Assistant Commissioner of Patents and Trademarks for review and substitution into the appropriate file wrappers. It is believed that no fee is required for submission of these papers. However, if a fee or petition is so required, then please consider this a petition therefor, and charge any fee required to Deposit Account No. 50-0861.

Respectfully submitted,

Date: May 24, 2001

Reg. No.: 33,916  
Tel. No.: 520-408-6350  
Customer No.: 23874



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Signature of Practitioner  
Huw R. Jones  
Ventana Medical Systems, Inc.  
3865 N. Business Center Drive  
Tucson, AZ 85705

Preliminary Classification:

Proposed Class:

Subclass:

**TRANSMITTAL LETTER TO THE U.S. DESIGNATED OFFICE (DO/US)--  
ENTRY INTO THE U.S. NATIONAL STAGE UNDER CHAPTER I**

PCT/US99/25109	26 October 1999 (26.10.99)	26 October 1998 (26.10.98)
International Application Number	International Filing Date	International Earliest Priority Date

TITLE OF INVENTION: Detection of Human Papilloma Virus in Papanicolau (Pap) Smears

APPLICANT(S) FOR DO/US: Light, Elizabeth S.; Nuovo, Gerard

**Box PCT**

Assistant Commissioner for Patents

Washington D.C. 20231

**ATTENTION: DO/US**

1. Applicant herewith submits to the United States Designated Office (DO/US) the following items under 35 U.S.C. Section 371:

This express request to immediately begin national examination procedures (35 U.S.C. Section 371(f)). The U.S. National Fee (U.S.C. Section 371(c)(1)) and other fees (37 C.F.R. Section 1.492), as indicated below:

---

**CERTIFICATION UNDER 37 C.F.R. SECTION 1.10\****(Express Mail label number is mandatory.)**(Express Mail certification is optional.)*

I hereby certify that this paper, along with any document referred to, is being deposited with the United States Postal Service on this date **June 26, 2000**, in an envelope as "Express Mail Post Office to Addressee," mailing Label Number **EL262636000US**, addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231.

Tandala R. Nobles*(type or print name of person mailing paper)*Tandala R. Nobles

Signature of person mailing paper



## 2. Fees

CLAIMS FEE*	(1) FOR	(2) NUMBER FILED	(3) NUMBER EXTRA	(4) RATE	(5) CALCULATIONS
BASIC FEE	TOTAL CLAIMS	22 - 20 =	2	x \$18.00 =	\$36.00
	INDEPENDENT CLAIMS	1 - 3 =	0	x \$78.00 =	\$0.00
	MULTIPLE DEPENDENT CLAIM(S) (if applicable) + \$260				\$0.00
	The international search fee, as set forth in Section 1.445(a)(2) to be paid to the US PTO acting as an international Searching Authority:  has been paid (37 CFR 1.492(a)(2)) ..... \$690.00				\$690.00
SMALL ENTITY	Total of above Calculations				= \$726.00
	Reduction by 1/2 for filing by small entity, if applicable. Affidavit must be filed (note 37 CFR 1.9, 1.27, 1.28).				- \$363.00
	Subtotal				\$363.00
	Total National Fee				\$363.00
	Fee for recording the enclosed assignment document \$40.00 (37 CFR 1.21(b)). (See Item below). See attached "ASSIGNMENT COVER SHEET".				\$0.00
TOTAL	Total Fees enclosed				\$363.00

Please charge Account No. 50-0861 in the amount of \$363.00.

A duplicate copy of this sheet is enclosed.

3. A copy of the International application as filed (35 U.S.C. Section 371(c)(2)) is not required, as the application was filed with the United States Receiving Office.

4. A translation of the International application into the English language (35 U.S.C. Section 371(c)(2)) is not required as the application was filed in English.

5. An oath or declaration, including power of attorney, of the inventor (35 U.S.C. Section 371(c)(4)) complying with 35 U.S.C. Section 115 is submitted herewith, and such oath or declaration is attached to application.

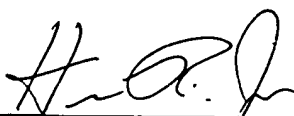
## II. Other document(s) or information included:

6. An international Search Report or Declaration under PCT Article 17(2)(a) is not required, as the application was searched by the United States International Searching Authority.

7. An Information Disclosure Statement under 37 C.F.R. Sections 1.97 and 1.98 will be transmitted within THREE MONTHS of the date of submission of requirements under 35 U.S.C. § 371(c).

Date: June 26, 2000

Reg. No.: 33,916  
Tel. No.: 520-408-6350  
Customer No.: 23874

  
\_\_\_\_\_  
Signature of Practitioner

Huw R. Jones, Esq.  
Director, Intellectual Property  
Ventana Medical Systems, Inc.  
3865 North Business Center Drive  
Tucson, AZ 85705

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Light, Elizabeth S.; Nuovo, Gerard J.

Application No.: PCT/US99/23815

Filed: 26-OCT-1999

For: Detection of Human Papilloma Virus in Papanicolau (Pap) Smears

STATEMENT  
CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(c-f) and 1.27(b-d))

Assistant Commissioner for Patents  
Washington, D.C. 20231

With respect to the invention described in application no. PCT/US99/25109, filed October 26, 1999.

I. IDENTIFICATION AND RIGHTS AS A SMALL ENTITY

I hereby state that I am an official of the small business concern empowered to act on behalf of the concern identified below:

Ventana Medical Systems, Inc.  
3865 N. Business Center Drive  
Tucson, AZ 85705

and that the above identified small business concern qualifies as a small business concern, as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under Sections 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

II. OWNERSHIP OF INVENTION

I hereby state that rights under contract or law remain with and/or have been conveyed to the above identified organization

EXCEPT, that if the rights held are not exclusive, each individual, concern or organization having rights to the invention is listed below and no rights to the invention are held (1) by any person who could

not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, (2) any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or (3) a nonprofit organization under 37 CFR 1.9(e).

### III. ACKNOWLEDGEMENT OF DUTY TO NOTIFY PTO OF STATUS CHANGE

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

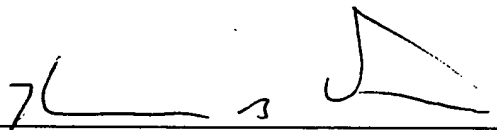
### IV. DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

### V. SIGNATURE

Kendall B. Hendrick  
Vice President and General Manager  
Research & Development  
3865 North Business Center Drive  
Tucson, AZ 85705

SIGNATURE



DATE

6/26/00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

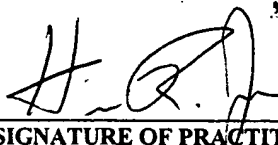
In re application of: Light, Elizabeth S.; Nuovo, Gerard J.  
Application No.: PCT/US99/25109  
Filed: 26-OCT-1999  
For: Detection of Human Papilloma Virus in Papanicolau (Pap) Smears

TRANSMITTAL LETTER

Assistant Commissioner for Patents  
Washington, D.C. 20231

Applicant herewith submits the following items for review by the United States Patent Office:

1. Response to Invitation to Correct Defects in International Application.
2. Petition and fee for extension of time (37 C.F.R. Section 1.126(a)).

  
SIGNATURE OF PRACTITIONER

Reg. No. 33,916

Tel. No.: (520) 408-6350

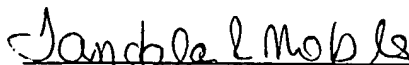
Customer No.: 23874

Date: September 11, 2000

Huw R. Jones, Esq.  
Ventana Medical Systems, Inc.  
3865 N. Business Center Drive  
Tucson, AZ 85705

CERTIFICATION UNDER 37 C.F.R. SECTION 1.10  
(Express Mail label number is mandatory.)  
(Express Mail certification is optional.)

I hereby certify that this paper, along with any document referred to, is being deposited with the United States Postal Service on this date September 11, 2000, in an envelope as "Express Mail Post Office to Addressee," mailing Label Number EL262635914US, addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231.

  
Signature of person mailing paper  
Tandala R. Nobles, Legal Assistant

**Practitioner's Docket No. 142/003/PCT**

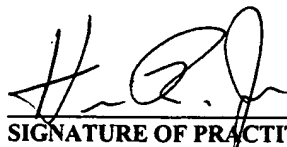
**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:     Light, Elizabeth S.; Nuovo, Gerard J.  
Application No.:         PCT/US99/25109  
Filed:                    26-OCT-1999  
For:                      **Detection of Human Papilloma Virus in Papanicolau (Pap) Smears**

**RESPONSE TO INVNTATION TO CORRECT DEFECTS  
IN INTERNATIONAL APPLICATION**

**Assistant Commissioner for Patents  
Washington, D.C. 20231**

With respect to the Invitation to Correct Defects in the International Application, attached is a copy of the Combined Declaration and Power of Attorney, which was filed in this case. Please be advised that all Applicants in this matter have signed the Combined Declaration and Power of Attorney.

  
\_\_\_\_\_  
SIGNATURE OF PRACTITIONER

Reg. No.         33,916

Tel. No.:       (520) 408-6350

Customer No.: 23874

Date:           September 11, 2000

Huw R. Jones, Esq.  
Ventana Medical Systems, Inc.  
3865 N. Business Center Drive  
Tucson, AZ 85705